

# **The Australian approach to intellectual property; Myriad on Appeal in Australia**

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**Christopher DNetto  
Macquarie University**

**Produced for the international Genetically Engineered Machine (iGEM)  
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## Foreword

This document provides an overview of the patents in Australia in regard to synthetic biology. It is intended to help future iGEM teams understand the Australian legal framework around this emerging industry. It is written to the best of my research and experience as an undergraduate law student, and contains an overview and brief discussion of the relevant law. I have tried to steer away from discussion of how the law 'ought to look', in favour of 'what the law is'. The latter question is of greater importance for researchers and undergraduate students involved in the practice itself. In contrast, the former question is one of jurisprudence, which has been extensively written about by the iGEM community, and the broader scientific community, whose arguments may be adopted by Australian policy makers. It will be briefly considered to introduce the direction that Australian intellectual property law has taken at the start of the 21<sup>st</sup> century.

### 1.1 Introduction – Intellectual Property

Intellectual property is a hard concept to define. It is readily described in bywords such as patents and copyright, reflecting the various interests and rights that they protect. Accordingly, the law provides protection for these rights and interests under intellectual property legislation, effectively protecting the economic investments in creative efforts that a person may undertake (Stewart, Griffith, Bannister, & Liberman, 2014), (Davison, Monotti, & Wiseman, 2011). Australian statutes therefore create and regulate intellectual property to encourage and reward innovation, protecting inventions in order to provide a competitive advantage to businesses (Australian Intellectual Property Office, 2014).

Synthetic biology is commonly described as an approach to engineering biology (Endy, 2012), whereby functional gene sequences (parts) are isolated, inserted or modified in order to create a new or existing system. There has been controversy and debate regarding whether a patent or open-source system is desirable for balancing the growth of the field and the distribution of its rewards (Nelson, 2014);- or even whether (as the author believes) both systems in tandem are best for achieving these goals (Calvert, 2012). This apparent dichotomy has been the basis for Australian legal cases, where Australian courts have reconsidered the nature of patents in the wake of the landmark US supreme court decision that ruled that naturally isolated genetic material is not a suitable candidate for a patent under US law (*Association for Molecular Pathology v. Myriad Genetics*, 2013) (2013).

## 2.1 Overview of Judicial and Legislative Framework

The findings and decisions of the Australian judiciary (ie - courts) are made in accordance to the rules of interpreting statute (legislation). The Australian constitution requires a separation of powers between judicial and legislative powers, restricting courts to the interpretation of laws in accordance to the intent;- and preventing courts from creating new law (making a decision that departs from what Parliament, the legislative body, has decided (*R v Kirby; Ex parte Boilermakers & Society of Australia* (“*Boilermakers’ case*”), 1956). Consequently, when courts are challenged by new areas of technology or novel cases, inadequacies of statute to address these cases may be brought to light.

Australian courts interpret the following domestic statutory instruments in considering intellectual property:

- Patents Act 1990
- Patents Regulations 1991
- Trade Marks Act 1995
- Trade Marks Regulations 1995
- Designs Act 2003
- Designs Regulations 2004
- Plant Breeder's Rights Act 1994
- Plant Breeder's Rights Regulations 1994

Of these, the first two are of primary relevance to synthetic biologists, and the final two have been used to regulate genetic modifications to plants.

## 2.2 Legislative adaptation to the 21<sup>st</sup> century

Australian Law Reform Commission (a body that does not hear court decisions but instead reviews decisions and considers the basis for and future of Australian law) formally considered gene patenting in 2004. They concluded that the law as it stood did not constrain against gene patents and considering options for reform(Australian Law Reform Commission, 2004). No reform to modify the patent act to affect a change in policy stance has been made by Parliament. A bill prohibiting patenting of human genes proposed in 2010 was not passed. There was support from both sides of debate for a research use exemption for gene patents, (Dr Lavelle, submitting on behalf of AusBiotech) but not for a general exemption of human patents to genes(Office Committee Hansard, 2011). The *Intellectual Property Amendment (Raising the Bar) Bill 2011* s119C enables researchers to utilise patented genetic material for experimental purposes in Australia. Consequently,

research on or involving patented gene sequences is no longer precluded by the presence of a validly formed patent.

No attempts to enshrine an exemption for commercial purposes patents in regard to human genes were made by Parliament. However, even if an exemption was made for human genes, it is not likely to apply to commercial applications of synthetic biology. There has been little support from parliamentarians for a general exemption for gene patents for non-human genetic material, although this issue has not been formally considered. This may be because there are less strong ethical and social reasons by which the economical imperative into research may be resisted for non-human organisms and genetic material (Lawson, 2002).

Human genomics involves in diagnosing genetic causes of disease (matters crucial to human health), where patents blocking research may block further advances and research to improve diagnostic and corrective procedures. In contrast, patents on bacterial systems derived from patented genes are unlikely to block access of people to diagnostic healthcare. This key difference may form a jurisprudential basis by which prokaryotic genetic material may be patented for commercial purposes whereas by human eukaryotic genetic material may not.

## **2.3 The 2013/2014 Australian Response to Myriad**

The US Myriad case in 2013 was the catalyst for testing the non-binding position of the Australian Law Reform Commission (ALRC). The first landmark decision considering whether a gene was a valid subject for a patent in Australia was handed down in *Cancer Voices Australia v Myriad Genetics Inc.* (2013), confirming that genes were patentable under the *Patent Act 1990*. This decision has been affirmed on appeal in *D'Arcy v Myriad Genetics Inc.* (2014). The High Court upheld the lower court's reasoning that genetic material was modified by isolation from its natural state. It therefore fulfilled requirements that there be a method of manufacture leading to an 'artificial state of affairs which has economic benefit', and was therefore patentable. That it was derived naturally and occurs naturally is no exception, as the process of isolating the gene modifies it to a chemical sequence that is not found naturally.

Thomas J's opinion from the US Supreme court decision, where isolation of a natural product is not sufficient for 'isolation', was not of relevance for Australian courts, as the statutes qualifying patentable material differ substantially. The US Supreme court considers the information encoded by the genes, namely, the base pairs contained within the BRCA1/2 genes, and this information was considered to have been isolated naturally. In contrast, Australian legislation required a consideration of the gene product, not the information that it contained. The High Court of Australia therefore upheld that genes, as a

result of artificial alteration in isolation, are valid subjects of genetic material. This is in accordance to Australian case law on the matter, primarily *National Research and Development Corporation v Commissioner of Patents* (1959) 102 CLR 252, from which the requirement for manufacture leading to an artificial state of affairs arises.

Crucially, the reasoning behind the High Court's decision in D'Arcy that confirms human gene patentability in Australia is also accessible to patents on genes of prokaryotes. The genomic elements coding for useful proteins, even when set apart to their expression host, are isolated into a form not found in nature. **It is therefore likely the case that the functional genes within the iGEM used term 'biobrick', even when taken separately to their antibiotic backbone, promotor regions and restriction sites, would be considered a valid subject for a patent in Australia under current law.** Additionally, there is the capacity for corporate patenting in Australia over functional gene sequences, by which a functional sequences, and variations upon them, may be patented, restricting their use by other researchers. There is therefore no functional difference in Australian law in regards to the source of genetic material: human eukaryotic genetic material is as much a candidate for a patent as prokaryotic DNA.

### 3.1 Summary

The main concepts of Australian intellectual property law as it applies to iGEM participants and those interested in genetic patent law are as follows:

- Intellectual property laws in Australia recognise international and domestic patents. International patents made to valid institutions are protected in Australia.
- In Australia, genes are valid subjects for patents. Isolated genes will fulfil the criteria put forward by the High Court – that researchers have created an artificial state of affairs, or chemically modified the DNA in isolating a genetic sequence.
- A patented gene is available for 'free use' for research purposes in Australia as a result of recent amendments to the Patents Act 1990. Teams in iGEM are in theory researchers, partaking in the competition for education purposes and to advance knowledge, consistent with the wording of the exception. Australian iGEM teams should take care, however, not to submit patented parts to the registry, or to introduce a commercial aspect to their work if they are using patented parts, as these may take them outside of the field of research, and they will be in violation of patent. iGEM teams in Australia must take care to ensure they do not leave the statutory protection offered to researchers.

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